Supreme Court, U.S.
FILED
FEB 20 1998
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No. 97-1201

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Petitioner,

v.

ELI LILLY AND COMPANY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Should the Court overturn as an abuse of discretion a decision of the Judicial Panel on Multidistrict Litigation ("JPML") consolidating five patent-related actions between Genentech Inc. ("Genentech"), the Regents of the University of California ("UC"), and Eli Lilly and Co. ("Lilly"): (1) where UC did not raise this issue before this Court by extraordinary writ as contemplated by 28 U.S.C. § 1407(e) and 28 U.S.C. § 1651; and (2) where there were hundreds of days of overlapping depositions, one of the patents asserted against Lilly by Genentech was the basis for Genentech's and Lilly's challenges to the validity and enforceability of UC's patents, and where the actions all required an understanding of complex biotechnology?

2. Should the Court reverse as an alleged violation of 28 U.S.C. §§ 1407(a) and 1404 an order of the multi-district transferee Court transferring the case to itself for trial even though: (1) UC waived this alleged defect by failing to raise it in its principal brief before the Federal Circuit; (2) UC failed to raise as one of its Questions Presented before this Court the propriety of the Federal Circuit's finding of waiver; and (3) the self-transfer practice is rooted in well established federal procedure and is not inconsistent with the spirit of the statute?

3. Are the Eleventh Amendment concerns raised by UC implicated where a state voluntarily enters the federal court system by suing a third party for patent infringement?

PARTIES TO THE PROCEEDING BELOW

The parties are Petitioner, Regents of the University of California, and Respondent, Eli Lilly and Company. Eli Lilly and Company possesses neither a parent company nor any non-wholly owned subsidiaries.

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OPINIONS BELOW

In addition to the opinions cited by UC, the opinion of the district court on the merits is reported at 39 U.S.P.Q.2d 1225 (S.D. Ind. 1995), and is annexed as Appendix A to Lilly's conditional cross-petition for certiorari served concurrently herewith.

STATEMENT OF THE CASE

I. INTRODUCTION

Contrary to UC's assertion that its scientists "paved the way for the production of recombinantly produced human insulin,"[1] it was Lilly and *not* UC that was the first to produce a safe and steady supply of human insulin created using "recombinant DNA" technology. Recombinant human insulin was developed and commercially introduced as the result of a collaborative project between Lilly and Genentech to which UC's scientists contributed *nothing*. Genentech, not UC, made and holds the basic patent on the recombinant DNA utilized by Lilly to make human insulin and human proinsulin. Lilly has already paid millions of dollars to Genentech for the right to practice under that patent.

UC nonetheless attempted to reap where it had not sown by suing Lilly in 1990 for allegedly infringing United States Patent Nos. 4,652,525 ("the '525 patent") and 4,431,740 ("the '740 patent"), seeking hundreds of millions of dollars for its alleged contribution to Lilly's sales of recombinant human insulin. After seven long years, both the United States District Court for the Southern District of Indiana and the United States

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[1] UC Pet. at 3.

Court of Appeals for the Federal Circuit thoroughly rejected such assertions by UC.

Throughout the litigation, UC sought to cloak itself in the mantle of a "pioneer." (UC Pet. at 2-3.) Yet, the evidence before the trial court established that the patents UC sought to enforce were rooted in inequity and deceit. While UC was the first to clone pieces of rat insulin DNA, it has now been proven that UC's original work upon which its patent position is based was conducted in knowing and willful violation of the applicable federal safety regulations governing recombinant DNA research. (Lilly Cross-Pet. at 3-9.) While UC's competition waited for government certification of the safety of the tools used in their recombinant DNA experiments, UC went forward using materials it knew had not been certified as safe by the government. *Id.* at 5-7. UC then misrepresented the origins of its data to the public, the National Institute of Health ("NIH"), the United States Senate, the United States Patent and Trademark Office ("PTO"), and the federal district court before which this action was tried, falsely claiming that the data had been obtained using certified materials. *Id.* at 5-8.

The trial court found UC's conduct sufficiently reprehensible that it refused to enforce the affected patent. *Id.* at 8-9. While the Federal Circuit reversed the trial court's unenforceability holding in the apparent belief that the misrepresentations were not material to any technical ground of unpatentability, it did not reverse as clearly erroneous any of the underlying factual findings of the trial court. (UC Pet. App. A at 23.)[2]

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[2] The Federal Circuit's treatment of the unenforceability issue represents a profoundly unwise public policy. It creates a large economic incentive for scientists to violate applicable federal safety regulations in the race for the vast economic reward associated with

Although UC's '525 patent purported to claim *all* the naturally occurring DNA sequences for proinsulin appearing in *any* mammal, UC had only experimentally determined and described a portion of the proinsulin DNA sequence for *rats*. The Federal Circuit, affirming the decision of the district court, specifically held that because, *inter alia*, one could not predict the structure of human or other mammalian DNA sequences based solely on the rat sequence, UC failed to demonstrate that it had actually invented the broad subject matter claimed by the '525 patent. (UC Pet. App. A at 17.) Accordingly, the Federal Circuit held that the claims of the '525 patent, which purported to encompass human DNA, were invalid for failing to satisfy the written description requirement of 35 U.S.C. § 112. *Id.*

Likewise, regarding UC's '740 patent, the Federal Circuit found that, during prosecution before the PTO, UC surrendered coverage of DNA sequences of the sort utilized by Lilly to produce human proinsulin. (UC Pet. App. A at 28.) Therefore, relying in part on this Court's decision in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S. Ct. 1040, 1049-51 (1997), the Federal Circuit held that UC could not recapture such subject matter in an infringement action. (UC Pet. App. A at 32.)

Without even challenging the merits of these decisions, UC seeks before this Court to undo the seven years of litigation it vigorously pursued against Lilly by raising alleged defects in *venue*. Yet, the Southern District of Indiana was undeniably a *proper* venue for the litigation. As the district in which Lilly

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securing U.S. patents on the fruit of illicit experimentation. Because this issue is of significant importance to the analogous current debate regarding the regulation of the cloning of human beings, Lilly has sought review in this Court, by way of a cross-petition for writ of certiorari filed concurrently herewith, of the Federal Circuit's enforceability holding.

has its principal place of business, it was a forum in which the infringement suit could have been brought originally under 28 U.S.C. § 1400(b). The Indiana district court also had both subject matter jurisdiction under 28 U.S.C. § 1338(a) and personal jurisdiction over Lilly. UC does not dispute these facts but instead complains about the particular procedural mechanisms that were used to transfer the case from the Northern District of California to the Southern District of Indiana. Specifically, UC challenges the validity of (1) an order by the JPML consolidating for pretrial proceedings UC's lawsuit against Lilly with four other factually related actions involving UC, Lilly, and Genentech pursuant to 28 U.S.C. § 1407, and (2) an order by the Southern District of Indiana transferring the trial venue from the Northern District of California to the multidistrict forum in the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a).

There is, however, nothing remarkable about these two orders that justifies review by this Court. As will be discussed below, these orders were proper, were based on the particular factual circumstances of the parties, were in accordance with well-established law, and manifestly served the interests of justice by promoting judicial economy. Furthermore, the particular alleged defects in these orders raised by the first and second questions presented in UC's certiorari petition have *not* been properly presented to this Court for review. UC's third question presented in its petition asserts that the two transfer orders somehow violated UC's purported Eleventh Amendment immunity. However, contrary to UC's protestations, the Eleventh Amendment to the Constitution simply has no bearing on the instant case. Here, UC was a willing *plaintiff* in the litigation it initiated against Lilly, *not* a defendant compelled to litigate in federal court against its will. Thus, UC's reliance on principles of sovereign immunity are misplaced and are at odds with nearly two hundred years of precedent in this Court.

II. LITIGATION HISTORY

In *The Regents of the University of California v. Eli Lilly and Co.*, UC sued Lilly in the Northern District of California for allegedly infringing its '525 and '740 patents. (UC Pet. App. A at 3.) Upon motion by Genentech, the JPML transferred the case in 1992 to the Southern District of Indiana pursuant to 28 U.S.C. § 1407 for coordinated pretrial proceedings with four other cases involving closely related technology, factual issues, documents, and witnesses.

Contrary to UC's contentions before this Court that there was "no common issue of material fact or law," the JPML specifically found that each action, in addition to requiring an understanding of recombinant DNA technology, "will present *factual questions that overlap with the other actions in this docket.*" (UC Pet. at i and App. E at 65, emphasis added.) The JPML explained that there were then thirty-five depositions common to all five actions, "issues of patent validity pertaining to three patents that will be present in all actions, and a contractual settlement agreement whose interpretation will be involved in all actions." *Id.* Based on these findings, the JPML correctly found that "[c]entralization under Section 1407 is thus necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary." *Id.* Indeed, the JPML's decision was correct as there were ultimately *hundreds* of days of depositions which were attended by counsel for UC, Genentech, and Lilly.[3]

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[3] UC incorrectly asserts that the JPML's decision was inconsistent with the previous decision of the Northern District of California. Contrary to UC's contention, Lilly had *not* previously moved to transfer the case under § 1404(a) to the Southern District of Indiana. Lilly had instead moved to *dismiss* the case or in the *alternative* transfer because

Not satisfied with the JPML's decision, UC petitioned the Federal Circuit for a writ of mandamus to vacate the consolidation order. The Federal Circuit denied UC's request, finding that there was a sufficient basis for the JPML's decision due to numerous common factual questions between the actions, including the following:

> *Regents v. Lilly* (California) is described as involving commercial activities of Lilly in producing human insulin using, in part, technology transferred to it by Genentech--this technology transfer partly underlies *Genentech v. Lilly* (Indiana). The agreements between the Regents and Lilly are involved in *Regents v. Lilly* (California), *Genentech v. Lilly* (Indiana), *Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana). A settlement agreement between the Regents and Genentech appears to be pertinent to *Regents v. Lilly* (California) and *Genentech v. Lilly* (Indiana). Various Genentech patents involved in *Lilly v. Genentech* (Indiana) are said to be asserted as invalidating prior art in *Regents v.*

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it believed venue in the Northern District of California was *not proper* under 28 U.S.C. §§ 1391(c) and 1400(b). *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 734 F. Supp. 911, 912 (N.D. Cal. 1990). Likewise, although the Northern District of California did deny Lilly's motion to consolidate two of the cases in California between UC, Lilly, and Genentech, the district court *did* consolidate discovery in the two cases by transferring management of all discovery disputes to a single magistrate. 21 U.S.P.Q.2d 1201, 1208 (N.D. Cal. 1991). Accordingly, the Northern District of California's decision to consolidate the two cases for discovery is perfectly consistent with the JPML's decision to consolidate these two cases and the remaining three in Indiana for pretrial proceedings.

> *Lilly* (California), *Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana).

(UC Pet. App. B at 54-55.) Accordingly, based on these numerous relationships, the Federal Circuit held that UC failed to demonstrate that the JPML's decision was an abuse of discretion or a usurpation of judicial authority and denied UC's mandamus petition.

UC also challenged the JPML's consolidation on the grounds that it violated the Eleventh Amendment to the Constitution. The Federal Circuit, citing *United States v. Peters,* 9 U.S. (5 Cranch) 115, 139 (1809) (Marshall, J.), rejected this contention as well, holding that "[t]he Eleventh Amendment is not designed to give procedural advantage to State litigants, but to shield states from unconsented actions against them." (UC Pet. App. at 52). By commencing a suit against Lilly in federal court, the Federal Circuit explained, "the Regents, like all litigants, become subject to the Federal Rules, including the procedural efficiencies administered by the Multidistrict Panel." *Id.* UC accepted the Federal Circuit's ruling and did not seek further review in this Court by extraordinary writ as contemplated by 28 U.S.C. § 1407(e) and 28 U.S.C. § 1651.

After approximately two more years of discovery, and after the Southern District of Indiana—the multidistrict forum—had considered and denied *two* complex summary judgment motions brought by Lilly, the district court, pursuant to 28 U.S.C. § 1404(a) transferred the trial venue of the case to the Southern District of Indiana based primarily on considerations of judicial economy and the fact that the convenience of the parties and witnesses did not dictate a contrary forum. In rendering its decision, the district court

specifically found that (1) it had already gained an understanding of the complex technical issues involved in the case and it would be a waste of judicial resources to have another court duplicate this effort, (2) judicial efficiency heavily favored transferring the action due to the trial court's growing familiarity with such issues, and (3) that the center of the accused infringing activity was located in the multidistrict venue and thus is the preferred forum for trial. (UC Pet. App. D at 60-63.) In opposition to the transfer, UC argued that the transfer would not serve the interests of justice or the convenience of the parties, but did *not* then urge that such a transfer would violate what UC belatedly alleges is the "clear" language of § 1407.

After an additional year of discovery, and after the Southern District of Indiana considered and denied a third summary judgment motion brought by Lilly and a summary judgment motion brought by UC, the case was finally tried before Senior Judge S. Hugh Dillin. After a careful review of a 13,000 page trial record developed during a two week trial, receipt and evaluation of expert testimony from both sides, and observation of the demeanor of six expert witnesses, five of the inventors named on UC's patents, and three of UC's attorneys, Judge Dillin issued a lengthy and detailed opinion holding that UC's patents were either invalid, unenforceable, or not infringed by Lilly. (Lilly Cross-Pet. at App. A.)

On appeal, UC raised *nine* issues before the Federal Circuit. UC challenged the trial court's findings that: (1) the '525 patent was invalid; (2) the '525 patent was unenforceable; (3) the '525 patent was not infringed under the doctrine of equivalents; (4) the '740 patent was not literally infringed; (5) or, in the alternative, the '740 patent was invalid; (6) the '740 patent was not infringed under the doctrine of equivalents; and (7) the '740 patent was unenforceable. UC also asserted that

(8) the district court's § 1404 transfer violated the Eleventh Amendment, and (9) the district court failed properly to evaluate the considerations set forth in § 1404. Although UC was obviously not bashful regarding raising issues for appellate review, UC completely *failed* in its principal brief before the Federal Circuit to raise the issue of whether the transfer of the trial venue to the multidistrict forum violated § 1407.

After Lilly had filed its principal brief before the Federal Circuit, UC placed a single sentence in its *reply* brief belatedly alleging that the § 1404 transfer allegedly violated the statutory language of § 1407. Moreover, it was not until less than a week before oral argument that UC first cited Judge Kozinski's dissent in *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation, 102 F.3d* 1524 (9th Cir. 1996), *cert. granted in part sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach,* 117 S. Ct. 1818 (1997), to the Federal Circuit. Because UC failed to raise this issue in its principal brief or at any earlier time during the litigation, Judge Bryson of the Federal Circuit specifically questioned UC's counsel, at oral argument, on the issue of whether this argument had been waived. In response to Judge Bryson's question regarding whether UC had properly raised this argument in its opening brief, UC's counsel— effectively *admitting* that it had waived the argument—stated "the exact answer to your honor's question is no we did not."

Seven months later, the Federal Circuit delivered a 33 page opinion holding that the '525 patent was invalid and that Lilly had not infringed the properly interpreted claims of the '740 patent. Regarding UC's challenge to whether the district court properly evaluated the criteria set forth in § 1404(a), the Federal Circuit explained that "in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial

economy may favor transfer to a court that has become familiar with the issues." (UC Pet. App. A. at 11.) The Federal Circuit also held, as it did before, that "the Eleventh Amendment applies to suits 'against' a state, not suits by a state," and that "we do not believe that the Court has ever so construed the Eleventh Amendment [as applying to suits brought by a state]." (UC Pet. App. A. at 9.)

Furthermore, the Federal Circuit, citing its own established precedent, found that UC, by failing to raise the issue in its opening brief, *waived* its argument regarding whether § 1407 allowed a multidistrict transferee court to transfer a case to itself for trial under § 1404(a). (UC Pet. App. A at 11-13.) UC filed a petition for reconsideration with a suggestion for rehearing in banc, which did not raise any of the issues now before the Court. Finally, UC filed its petition for writ of certiorari on January 21, 1998.

REASONS FOR DENYING THE WRIT

The Court should not expend its extremely limited resources by examining the propriety of the pretrial consolidation by the JPML, which is the subject of UC's first question presented in its petition. This issue has not been properly raised and is fundamentally a factual dispute not worthy of Supreme Court review. The JPML properly determined that, due to the many overlapping witnesses and the common factual issues involved in the actions between UC, Genentech, and Lilly, the five separate actions should be consolidated for pretrial proceedings to promote judicial economy and serve the interests of justice. On a petition for a writ of mandamus, the Federal Circuit in *1992* reviewed the merits of the consolidation order and after a full and fair hearing held that the JPML had not abused its discretion. Now, six years later, after voluminous discovery, a legally and

technically complex trial, and an appeal to the Federal Circuit, UC asks this Court to review the findings of the JPML and the Federal Circuit. UC, however, did not raise the validity of the multidistrict consolidation to this Court *at that time* as contemplated by § 1407(e) and § 1651. Accordingly, this Court should decline to consider at this late date the circumstances regarding the pretrial consolidation. Furthermore, and perhaps more importantly, this issue is simply not worthy of this Court's review. UC's argument represents a mere *factual* challenge to the findings of the JPML—findings that were approved by the Federal Circuit—regarding the interrelations between the five actions and does *not* raise a unique question of law warranting review by this Court.

UC's challenge to the Southern District of Indiana's so-called "self transfer"—the second question presented in UC's petition—is also not properly before the Court. UC contends in its petition that the allegedly "plain language and clear legislative history"[4] demonstrate that a § 1407 transferee court cannot transfer the case for trial to the multidistrict venue pursuant to 28 U.S.C. § 1404(a). This issue is currently before the Court in *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 117 S. Ct. 1818 (1997). However, UC fails to explain why, despite this alleged "plain language," it failed to raise this issue until after both parties had filed their principal briefs on the merits on appeal before the Federal Circuit. Since UC did not raise this issue in its opening brief, the Federal Circuit, following its own well-established precedent, held that UC had waived this venue argument. Thus, before this Court reaches this issue on the merits, it must first determine whether the Federal Circuit correctly found that UC waived this issue. This question, however, is not included in UC's petition for certiorari

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[4] UC Pet. at 17.

and is not "fairly included therein" under the rationale of *Yee v. Escondido,* 503 U.S. 519, 537 (1992). Accordingly, this Court should not even reach UC's second question. Moreover, even if the Court addresses this issue, it should not disturb the Federal Circuit's opinion because (1) UC did in fact waive this venue issue and (2) the self-transfer practice is not in conflict with the statutory framework for reasons cited by the respondent and supporting *amici* in the *Lexecon* case.

Finally, the Eleventh Amendment concerns raised by UC—UC's third question—simply have no bearing on the issues in this case. The Eleventh Amendment immunity to which UC clings simply does not apply where a state is a willing plaintiff in federal court. Accordingly, for all of the foregoing reasons, this Court should deny UC's petition for a writ of certiorari.

I. UC'S FIRST QUESTION DOES NOT WARRANT REVIEW BY THIS COURT

UC's first question asks whether the Federal Circuit erred by declining to overturn an order of the JPML, which consolidated for coordinated pretrial proceedings five then-pending lawsuits involving UC, Genentech, and Lilly. This question, however, does not merit further attention by this Court because: (1) UC failed to seek timely review of the Federal Circuit's denial of its petition for a writ of mandamus; and (2) the question raises mere factual issues that have already been considered and appropriately resolved by the JPML and the Federal Circuit.

A. Review Now Is Untimely

UC did not petition this Court to review the Federal Circuit's denial of its mandamus petition *at the time of the decision.* UC instead allowed the parties and the federal courts to expend years of effort in discovery, trial preparation, trial practice, and appellate practice, the results of which UC now finds unsatisfactory. If UC had a continuing objection to coordinated pretrial proceedings, it had a duty to raise those objections promptly before this Court by application for an extraordinary writ. Because UC did not do so, prudential considerations weigh heavily against reviewing the propriety of the JPML at this late date. In enacting § 1407(a), Congress sought "to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions."[5] Such centralized management, it was hoped, would avoid or minimize the possibility for conflict or duplication of discovery during pretrial proceedings. *Id.* at 1899-1900. Although Congress identified a number of factors relevant to the application of a § 1407(a) transfer, it recognized that such factors "do not lend themselves to precise measurement," and that "the informed discretion of the judiciary is the best method for resolving questions as to when and where cases should be transferred for pretrial [proceedings]." *Id.* at 1901.

Accordingly, to best effectuate its overall purpose of promoting judicial economy, Congress expressly opened, yet also carefully circumscribed, a specific path for judicial review of JPML decisions under § 1407(e). Under the express language of 28 U.S.C. § 1407(e), "[n]o proceedings for review

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[5] *See* H.R. No. 1130, 90th Cong., 2d Sess. 2 (1968), *reprinted in* 1968 U.S.C.C.A.N 1898, 1899.

of any order of the panel may be permitted except by extraordinary writ pursuant to the provisions of title 28, section 1651, United States Code." By limiting review to this procedural mechanism, dissatisfied litigants were given a simple choice: either pursue immediate judicial review, in the nature of mandamus under 28 U.S.C. § 1651, or go forward with pretrial proceedings in the transferee district.[6]

Although UC petitioned to the Federal Circuit for mandamus under § 1651, it did *not* seek review from this Court of the Federal Circuit's denial of its mandamus petition by extraordinary writ as contemplated by § 1407(e). 28 U.S.C. § 1651(a) undeniably provides this Court with the authority to act upon an appropriate application under § 1407(e).[7] Because an appropriate method of obtaining review by this Court existed at that time, UC should not be permitted to avoid the procedural mechanism specifically enacted by Congress for review of § 1407(a) transfer orders. Indeed, logic dictates that if UC desired to petition this Court for review, it should have done so at the time of the Federal Circuit's denial of its mandamus petition, *not* six years later—after discovery, a trial on the merits, and an appeal to the Federal Circuit. Review of the JPML's consolidation order at this late date utilizing the "normal" certiorari route would seriously conflict with Congress' intent of permitting review of the JPML's orders only in a manner which promotes the policy of judicial economy

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[6] 1968 U.S.C.C.A.N. at 1902 (mandamus "is more expeditious than appeal, and is consistent with the overall purposes of the proposed statute").

[7] Section 1651(a) states that "The Supreme Court . . . may issue all writs necessary or appropriate in aid of [its] jurisdiction[] and agreeable to the usages and principles of law."

underlying § 1407. Accordingly, this Court should decline to review UC's first question presented.[8]

B. UC's Challenge is Merely Factual

UC asserts that the JPML abused its discretion and/or exceeded its statutory authority by consolidating the five actions between Genentech, UC, and Lilly because—according to UC—there were no common factual questions involved in the actions. The fundamental flaw in UC's argument, however, is that the there *were* numerous factual overlaps between the actions, including *hundreds* of days of common depositions and *thousands* of common documents. Indeed, UC completely ignores the specific findings of the JPML and the Federal Circuit regarding these factual overlaps. (UC Pet. App. B. at 54-55; UC Pet. App. E at 65.)[9] In this regard, the JPML specifically stated that the five actions, in addition to requiring an understanding of recombinant DNA technology, "will present *factual questions that overlap with the other actions in*

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[8] Even if this Court determines that UC did not have to raise this issue to the Court at an interlocutory stage of the proceeding, UC should have raised this issue again to the Federal Circuit on appeal after trial. *See* Robert L. Stern et al., *Supreme Court Practice*, 198 (7th ed. 1993)("Denial of certiorari at the interlocutory stage of a proceeding is without prejudice to renewal of the questions presented when certiorari is later sought from the final judgment, *assuming the questions are properly preserved in the lower courts after the denial.*")(emphasis added). As UC chose not to raise this issue before the Federal Circuit, review here is no longer appropriate.

[9] Due to these factual overlaps, UC's reliance on *In re Repetitive Stress Injury Litigation*, 11 F.3d 368, 373 (2d Cir. 1993) is misplaced.

this docket." (UC Pet. App. E at 65, emphasis added.)[10] Thus, as UC's petition represents a mere factual challenge to the record already reviewed by the JPML and the Federal Circuit, it should not be reviewed by this Court pursuant to well-established precedent.[11]

II. UC's SECOND QUESTION REGARDING THE PROPRIETY OF SELF-TRANSFER IS NOT PROPERLY BEFORE THE COURT

A. UC Failed Properly to Present the Waiver Issue as a Question to this Court

This Court's Rule 14.1(a) specifically states that "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." Accordingly, "[t]he framing

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[10] Although Lilly could spend many pages discussing the numerous factual interconnections between the five actions, Lilly will merely note that published European patent application EPA-1929, the foreign counterpart of one of the patents that was in suit in the Indiana patent action between Genentech and Lilly (U.S. Patent No. 4,704,362 issued in the names of Itakura and Riggs) provided the basis for Lilly's defenses in the instant case that UC's '740 patent was both invalid and unenforceable and Genentech's defense in its litigation with UC that UC's growth hormone patent was unenforceable. Thus, one of the critical issues in all the cases was the scope and content of this patent's disclosure and the factual circumstances involving UC's knowledge of this patent.

[11] *Graver Tank & Mfg. Co., v. Linde Air Prod. Co.*, 336 U.S. 271, 275 (1949)(stating that "[a] court of law, such as this Court is, rather than a court for correction of error in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error"); *Goodman v. Lukens Steel Co.*, 482 U.S. 656, 665 (1987).

of the question presented has significant consequences" since the Court does not ordinarily "consider questions outside those presented in the petition for certiorari." *Yee v. Escondido,* 503 U.S. 519, 535 (1992); *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.,* 510 U.S. 27, 31-32 (1993). Although this rule is prudential in nature, the Court will only disregard it "in the most exceptional cases." There are two principal reasons for the rule: (1) it provides notice to the respondent of the grounds upon which the petitioner seeks certiorari; and (2) it assists the Court in granting certiorari in only those cases that enable the Court to "resolve particularly important questions." *Yee*, 503 U.S. at 535-36.

In the instant case, UC failed to present to the Court the question of whether the Federal Circuit erred in finding that UC waived the so-called *Lexecon* self-transfer argument. Instead, UC only raised the self-transfer issue on the merits: whether the language of § 28 U.S.C. 1407(a) permitted the multidistrict judge to transfer the trial venue of the case to the multidistrict forum under 28 U.S.C. § 1404(a). An almost identical situation was presented to the Court in the *Izumi* case. In *Izumi*, the petitioner presented one question for review by the Court: "Should the United States Court of Appeals routinely vacate district court final judgments at the parties' request when cases are settled while on appeal?" *Izumi*, 503 U.S. at 30. However, in order to reach this question, the Court first had to decide the following standing question later raised by petitioner: "Whether the court of appeals should have permitted Petitioner to oppose Respondents' motion to vacate the district court's judgment?" *Id.* The Court explained that if the later raised question is not fairly included in the initial question presented for review, then "Rule 14.1 would prevent us from reaching it." *Id.* at 31.

The Court found that the second question was *not* "subsidiary" or "fairly included" in the initial question, explaining that the later raised question is a threshold inquiry akin to a question regarding a party's standing, in "no way depends on the merits" of the case, and is "analytically and factually" quite different from the question on which review was granted. *Id.* at 31-32. Moreover, the Court noted that the analysis is not affected by the fact that the parties discussed the question in their briefs, stating that this "fact . . . does not bring that question properly before us." *Id.* at 31 n.5. Thus, this Court held that Rule 14.1(a) imposed a heavy presumption against considering the second question. Although acknowledging that there are exceptions to this general rule, the Court found that none of those exceptions applied because a decision on a motion to intervene—the later raised question—is a difficult one, is bound up in the facts of the case, and is unlikely to result in a new principle of law. *Id.* at 33. Therefore, since the later raised intervention issue needed to be addressed *before* the Court could address the question that was properly presented, the Court dismissed its writ of certiorari as improvidently granted. *Id.* at 34.

Likewise, this Court should not grant certiorari on the self-transfer issue raised by UC's second question presented. To reach this question, the Court must first hold that the Federal Circuit erred in finding that UC waived the self-transfer argument. However, as in *Izumi,* this threshold issue was *not* properly presented as a question to this Court. Moreover, the waiver issue is not "fairly included" in the question on the merits presented by UC. As was the case in *Izumi*, the waiver issue is a threshold inquiry which in no way depends on the merits of the case and is factually and analytically distinct from UC's second question on the merits. To determine that the Federal Circuit erred regarding the waiver issue, this Court would have to examine both the Federal Circuit's precedent on

briefing requirements and waiver and the factual circumstances regarding UC's failure to raise the self-transfer issue at any time before its reply brief at the Federal Circuit. This analysis is completely separate and distinct from the question of whether the language and legislative history of § 1407(a) allows self-transfer. Furthermore, there are not sufficient reasons in the instant case to overcome the "heavy presumption" against reviewing an issue not fairly included in the question presented. As in *Izumi*, the question regarding whether UC waived the issue is bound up in the facts of the case and is unlikely to establish a new principle of law. Moreover, the legal question raised by UC on the merits has already been raised in the *Lexecon* case. Thus, there is no compelling need for the Court to now address this issue. Accordingly, this Court should not reach this issue and thus should not grant certiorari on UC's second question presented.

B. UC Waived the Self-Transfer Argument Set Forth in its Second Question Presented

Even if this Court reaches the question of waiver, certiorari on the merits is not warranted. The Federal Circuit correctly found that UC waived this issue. UC asserts that the "plain language and clear legislative history of Section 1407(a)" indicates that the district court should have remanded the case to the Northern District of California rather than transferring the trial venue to the Southern District of Indiana pursuant to § 1404(a). (UC Pet. at 17.) However, UC provides no satisfactory explanation why, if the language is so clear, it first raised this issue in its reply brief before the Federal Circuit. In this regard, UC's position is remarkably different from that of the petitioner in *Lexecon,* which raised the issue regarding the statutory language of § 1407 by writ of mandamus to the Ninth Circuit immediately after the allegedly improper transfer and again to the Ninth Circuit on appeal of the merits. If Lexecon

could properly raise these arguments, there is apparently no reason why UC could not have done the same.

It is the well-established practice in the Federal Circuit, as in many other courts of appeals, that issues not raised in a party's principal brief are waived. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990) ("[A]n issue not raised by an appellant in its opening brief . . . is waived."); *see also Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 973 (Fed. Cir. 1986)("We note here that it is inappropriate for appellants to discuss in their reply brief matters not raised in either of the principal briefs."); *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1561 n.1 (Fed. Cir. 1994). For this reason, the Federal Circuit specifically questioned UC's counsel at oral argument regarding whether it had properly raised the self-transfer argument in its opening brief. As previously mentioned, *see* p. 9, *supra*, UC conceded that it did not raise this argument in its opening brief and thus effectively *admitted* that it waived the argument under well-established practice and precedent of the Federal Circuit.

In response, UC argues *not* that it had properly raised the issue of whether the language and legislative history of § 1407(a) precluded self-transfer, but instead that it had raised *other* venue challenges before the Federal Circuit. Specifically, UC cites its contentions that Judge Dillin failed properly to evaluate the criteria set forth in § 1404(a) (whether the transfer was for the convenience of the parties and in the interests of justice) and whether the transfer violated UC's alleged Eleventh Amendment immunity from suit. Indeed, UC suggests, citing *Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995), that even if the Federal Circuit correctly found that UC had waived this issue, review by this Court is still proper because UC had raised these other venue issues. (UC Pet. at 16-17.)

Yet, *Lebron* provides no support for UC's position. The Court in *Lebron* merely found that "once a claim is properly presented, a party can make any argument in support of that claim." 513 U.S. at 379. UC, however, did *not* raise its claim regarding the statutory language of § 1407 in a timely manner before the Federal Circuit. UC only challenged whether the district court correctly applied the criteria of § 1404 and whether such a transfer violated the Eleventh Amendment. In contrast, UC now seeks to broaden its claim to include *all* challenges to the venue of the trial. Such efforts should not be countenanced by this Court. Indeed, the Federal Circuit has a similar rule to the one cited in *Lebron* but nevertheless found that UC had waived this argument.[12]

Moreover, in an analogous situation, this Court has found that a claim regarding whether there had been a *regulatory* taking was analytically different and *not* fairly included in a claim regarding whether there had been a *physical* taking. *Yee,* 503 U.S. at 537. The Court specifically held that "[b]oth might be subsidiary to a question embracing both—Was there a taking?—but they exist side by side, neither encompassing the other." *Id.* In the same way, UC's arguments that Judge Dillin did not properly apply the criteria in § 1404(a) and that the transfer was unconstitutional do not encompass the analytically separate question of whether § 1407(a) requires remand.

Furthermore, the Court in *Lebron* specifically discussed the previous decision in *Yee* and distinguished *Yee* on the following grounds: (1) that it was possible in *Yee* to consider

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[12] *See Consolidated Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 814 (Fed. Cir. 1990) (judgment may be defended on any ground properly raised below).

whether there was a physical taking without inquiring into whether there was a regulatory taking but in *Lebron* it was "impossible" to consider whether Amtrack's government connections were sufficient to convert Amtrack from a private-entity into the Government without first determining that Amtrack was a private entity; and (2) that while in *Yee* "what would go to show a regulatory taking and what would go to show a physical taking were quite different," in *Lebron,* the elements that the Court would consider in determining whether Amtrack was converted into the Government or whether it was the Government to begin with are closely related and overlap. 513 U.S. at 381-82. In the instant case, it is obviously possible to determine the § 1404 issues raised by UC without considering the question of whether § 1407 requires remand since this is exactly what was done by the Federal Circuit. Moreover, as in *Yee*, the analysis of whether the transfer was for the convenience of the parties and in the interests of justice and whether it violated the Eleventh Amendment are separate and do not overlap with the question regarding the meaning of the language and legislative history of § 1407(a).[13] Accordingly, the Court's decision in *Lebron* does not excuse UC's failure to raise this issue before the Federal Circuit.

Finally, as to the merits of UC's position, it is Lilly's position that the JPML's rule allowing self-transfer by the § 1407 transferee court is consistent with both the text and legislative history of 28 U.S.C. § 1407 and serves the interests

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[13] In addition, another reason why the Court in *Lebron* decided to review the issue was that it was passed upon by the Second Circuit. *Id.* at 379; *Lebron v. National R.R. Passenger Corp.*, 12 F.3d 388, 390 (2d Cir. 1993)(holding that "Government action is most readily found when the conduct at issue is performed by a government entity . . . that is not the case here"). In the instant case, however, the Federal Circuit did not pass on the issue, finding that it had been waived by UC.

of justice. Indeed, contrary to UC's assertions, Lilly submits that the instant case graphically illustrates the proper functioning of the multidistrict litigation system, as envisioned by Congress, by disposing of unmeritorious claims in the most efficient and expeditious manner possible. Lilly's views on this issue are amply reflected in its *amicus* brief, as well as the brief of the Respondent in the *Lexecon* case. Lilly will not burden this brief with a recapitulation of those views. Suffice it to say that if this Court does not strike down the now well-established practice of self-transfer in the *Lexecon* case, UC's arguments will necessarily fail as a matter of law. Yet, even if this Court were to rule in *Lexecon* that self-transfer is improper, UC's petition must still be denied because UC, unlike the petitioner in *Lexecon*, waived this argument.

III. ELEVENTH AMENDMENT CONCERNS ARE NOT IMPLICATED BY THIS CASE

In its petition for certiorari, UC seeks to portray itself as a helpless state litigant whose sovereign immunity has been swept away by the flawed application of 28 U.S.C. §§ 1407 and 1404. UC contends that the JPML's pretrial consolidation under § 1407 and the transfer of the trial venue to the multidistrict forum under § 1404(a) deprived a sovereign of its right to select a forum for its litigation and thereby violated the Eleventh Amendment to the Constitution. (UC Pet. at 17-18.) This argument, however, flows from UC's erroneous view that principles of sovereign immunity are somehow implicated where a state is a *willing plaintiff* in federal court. UC's novel theory is not only directly contradicted by the jurisprudence of this Court but also subverts the very policies underlying the Eleventh Amendment.

The Eleventh Amendment was enacted as a direct response to this Court's decision in *Chisholm v. Georgia*, 2 U.S.

(2 Dall.) 419 (1793), which allowed a South Carolina citizen to *sue* the state of Georgia in federal court to recover debts for materials supplied during the Revolutionary War.[14] To overturn the result of this case, the Eleventh Amendment prohibits citizens of another state, or of the same state, from *suing an unconsenting state* in federal court. The Eleventh Amendment embodies the Constitutional policy that "each State is a sovereign entity in our federal system" and that "it is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent." *Seminole Tribe of Florida v. Florida*, 116 S. Ct. 1114, 1118 (1996). The sovereignty of the State of California, however, cannot be violated when, as in this case, the state itself purposefully chooses to bring suit in federal court. *United States v. Peters*, 9 U.S. (5 Cranch) 115, 139 (1809).

In *United States v. Peters,* Justice Marshall, writing only eleven years after the ratification of the Eleventh Amendment, discussed the scope of this doctrine in a case where the State of Pennsylvania had asserted that federal courts were without jurisdiction. In addressing the state's arguments, Justice Marshall specifically stated the following:

> The right of a state to assert, *as plaintiff*, any interest it may have in a subject, which forms the matter of controversy between individuals, in one of the courts of the United States, is not affected by this amendment; nor can it be so construed as to oust the court of its jurisdiction, should such claim be suggested. *The*

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[14] *Principality of Monaco v. Mississippi*, 292 U.S. 313, 325 (1934); *see* Erwin Chemerinsky, *Federal Jurisdiction*, § 7.2 at 330-32 (1989).

> *amendment simply provides, that no suit shall be commenced or prosecuted against a state.*

Id. at 139, emphasis added. Contrary to UC's assertions, this statement directly addresses and thoroughly rejects UC's assertion that the Eleventh Amendment applies where a state is a willing plaintiff in federal court. Indeed, UC has failed to cite one case in the two hundred years since its ratification where the Eleventh Amendment was invoked in a situation such as this where the state brought the suit.

The cases cited in UC's petition for certiorari involve situations where the state was the defendant, *not* the plaintiff.[15] Moreover, much of UC's cited authority pertains to the level of intent necessary for a state to effectuate a *waiver* of its Eleventh Amendment immunity. Such principles of *waiver* are simply not applicable because the Eleventh Amendment immunity does not apply where the state is a willing plaintiff. Moreover, the venue concern implicated by the cases cited by UC is whether the state consented to be sued in federal court or state court, *not* whether consent to proceedings in one federal court

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[15] *See e.g., Seminole Tribe v. Florida*, 116 S. Ct. 1114 (1996) (suit against State of Florida); *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89 (1984) (suit against officials of State of Pennsylvania); *Port Authority Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 307 (1990) (suit against entity created by States of New York and New Jersey); *Hans v. Louisiana*, 134 U.S. 1 (1890) (suit against state of Louisiana); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985) (suit against California State Hospital and California State Agency); *In re New York*, 256 U.S. 490, 496 (1921) (suit against state of New York).

could preclude transfer to another federal court as suggested by UC. [16]

Thus, the clear text of the Eleventh Amendment and the jurisprudence of this Court provide no support for UC's novel interpretation regarding the scope of the Eleventh Amendment immunity from suit. UC attempts to bolster its position by resorting to strained policy arguments. UC asserts that the Federal Circuit ignored "the broad principles underpinning the Amendment" and instead "focused myopically on the precise words," giving the Eleventh Amendment a "narrow, wooden, construction." (U.C. Pet. at 21-22.) UC, however, fails to demonstrate how the Federal Circuit's determination contravenes *any* important policy.

Indeed, the Federal Circuit's decision is perfectly consistent with this Court's precedent that citizens of the same state,[17] foreign sovereigns,[18] and federal corporations cannot *sue* a state in federal court.[19] All of these decisions reflect the

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[16] *See, e.g., Port Authority Trans-Hudson Corp.*, 495 U.S. at 307 (holding that the states of New York and New Jersey consented to be sued in *federal* court, rather than *state* court, and thereby waived their Eleventh Amendment immunity); *Pennhurst State Sch. and Hosp.*, 465 U.S. at 99 n.9 ("[T]he Court consistently has held that a State's waiver of sovereign immunity in its own [state] courts is not a waiver of the Eleventh Amendment immunity in the federal courts."); *Atascadero State Hosp.*, 473 U.S. at 241 ("[I]n order for a State statute . . . to constitute a waiver of Eleventh Amendment immunity, it must specify the State's intention to subject itself to suit in *federal court*.").

[17] *Hans v. Louisiana*, 134 U.S. 1 (1890).

[18] *Principality of Monaco v Mississippi*, 292 U.S. 313 (1934).

[19] *Id.* at 327.

policy that a sovereign should not be compelled into the courts of another sovereign against its will. These decisions have absolutely nothing to do with the instant case where a state voluntarily entered the federal court system by suing a third party. In this regard, the Federal Circuit specifically stated that "we do not believe that the Court has ever so construed the Eleventh Amendment" to apply to situations where the state is a willing plaintiff. (U.C. Pet. App. at 9.) Accordingly, the Federal Circuit—applying the uniform precedent of this Court—correctly held that "the Eleventh Amendment applies to suits 'against' a state, not suits by a state" and that "[t]he Eleventh Amendment is not designed to give procedural advantage to State litigants, but to shield States from unconsented actions against them." (U.C. Pet. App. at 9, 52.)

UC further argues that there is a "blurring" of the defendant-plaintiff roles in patent cases which somehow justifies an expansion of the Eleventh Amendment beyond its intended scope. As the patent holder, UC asserts that it must *defend* its patents against charges of invalidity and unenforceability. (UC Pet. at 24.) Thus, according to UC, its role in patent cases is like that of a traditional defendant. *Id.* UC's contentions are without merit. In this case, there was no legal charge or proceeding initiated by Lilly attacking UC's patents. There was only a refusal by Lilly to acquiesce in UC's assertion that it had a property right which Lilly was infringing. UC chose to go to federal court to enforce its asserted property right, just as every plaintiff in commercial civil litigation goes to court to assert some property or contract right which its adversary refuses to acknowledge. If UC's argument were accepted, the plaintiff in every such commercial case could be viewed as the *de facto* defendant, leading to a series of facially absurd results.

Moreover, contrary to UC's assertion, there is nothing that compels a state entity to own patents or to sue alleged infringers. UC suggests that "[i]n these days of diminishing public resources," state universities often patent their discoveries to create income for additional basic research. (UC Pet. at 19.) UC then asserts that it "must" file suit in federal court or forego an important public asset–hypothetical royalties from an alleged infringer. *Id.* at 20. Yet, UC fails to explain why a state cannot raise revenue for its university system in the traditional methods available to states, such as raising taxes or selling bonds. Lilly submits that expanding the Eleventh Amendment to provide states with procedural advantages in litigation is not the best or even a rational way to promote a state's educational system.

Furthermore, UC fails to acknowledge its ability to sell or otherwise *assign* its patents to a private entity for valuable consideration and let *that* entity sue the alleged infringer in federal court. This Court has specifically held that an assignee has standing to sue an alleged infringer without the presence of the assignor in the lawsuit. *Waterman v. MacKenzie*, 138 U.S. 252, 255 (1891)(holding that an assignment of the "whole patent, comprising the exclusive right to make, use, and vend the invention . . . vests in the assignee . . . a right to sue infringers . . . in the name of the assignee alone"); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 873-74 (Fed. Cir. 1991). By assigning its patents, UC can still collect revenue from its technical developments and avoid the alleged indignity of litigating in federal court.

On the other hand, if a state university sets aside its cloak of sovereign immunity in order to sue alleged infringers in federal court, it must be bound by the federal rules and applicable statutes. Any other rule would transform the state into a "super" litigant, enabling it to use its sovereign immunity

to dictate which rules and/or statutes it chooses to follow. Such a rule would seriously undermine principles of fundamental fairness critical to the proper operation of the federal courts by drastically increasing the power of states at the expense of other litigants.

Accordingly, UC is *not* entitled to choose the forum in which it will proceed to trial, but is *only* entitled to choose to stay out of the federal court system entirely. Once a state voluntarily enters the federal court system by *suing* another party, it loses its Eleventh Amendment protection and subjects itself to the same rules and statutes that apply to all other litigants, including 28 U.S.C. §§ 1404 and 1407. As aptly stated by the Federal Circuit, "Upon entering the litigation arena the Regents, like all litigants, become subject to the Federal Rules." (UC Pet. App. B at 52.)

Finally, UC contends that the Eleventh Amendment should preclude transfer to another venue because "the accused infringer could gain through a transfer motion what it could not accomplish through the early filing of a declaratory judgment action." (UC Pet. at 25.) UC's argument is a logical non sequitur. Assuming, as UC does, that Eleventh Amendment immunity would shield a state from a declaratory judgment action brought by a private citizen,[20] it necessarily follows that the citizen cannot pick the forum for a suit he or she is not

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[20] This issue of whether Congress has the power to abrogate a state's Eleventh Amendment immunity and subject it to suit under 35 U.S.C. §§ 271(h) of the patent laws is currently before the Federal Circuit as an appeal of Judge Dillin's decision in *Genentech, Inc. v. Regents of the University of California*, 939 F. Supp. 639, 646 (S.D. Ind. 1996). This question need not be addressed by the Court at this time because the Eleventh Amendment simply does not apply where the state is a willing plaintiff in federal court.

entitled to file. The state may thus stay out of federal court if it so chooses. If a state chooses, however, to enter the federal court system by voluntarily appearing as a plaintiff, then every defendant has the right to ask the federal court to conduct the litigation in a more convenient forum under 28 U.S.C. §§ 1404 and/or 1407, and the federal courts have acquired the authority over the state to make such decisions and issue appropriate orders effecting those decisions.

CONCLUSION

For the foregoing reasons, Lilly urges the Court to deny UC's petition for a writ of certiorari in its entirety.

Respectfully submitted,

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